DEPARTMENT OF HEALTH & HUMAN SERVICES
New York District

Food & Drug Administration
300 Pearl Street, Suite 100
Buffalo, NY 14202

m14859m

WARNING LETTER NYK 2001- 19

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

November 13, 2000

Facility ID: 149344

Ronald Mullahey
Chief Executive Officer
Vassar Brothers Hospital
45 Reade Place
Poughkeepsie, NY 12601

Dear Mr. Mullahey:

Your facility was inspected on October 26, 2000 by a representative of the New York State Department of Health, acting in behalf of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 finding at your facility:

- ***Phantom QC records were missing for four weeks for the Lorad Medical Systems, Inc., Unit 2, MIII, located in the Mammography Room.***

The specific problem noted above appeared on your MQSA Facility Inspection Report which was issued to your facility at the close of the inspection. This problem is identified as Level 1 because it identifies a failure to meet a significant MQSA requirement.

On October 31, 2000, Susan Davis, Executive Vice President and Chief Operating Officer, responded by letter to the above mentioned Level 1 finding. This response appears adequate, and the impact of your corrective action will be assessed in a future inspection; however, we would like to emphasize the following:

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to

substantially comply with, or each day of failure to substantially comply with, MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

In addition, a repeat Level 3 finding was listed on the inspection report provided at the close of the inspection. The repeat Level 3 finding is:

- ***The required personnel qualification documents were unavailable during the inspection.***

It is necessary for you to act on this additional matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you receive this letter:

- The specific steps you have taken to correct the repeat Level 3 violation noted in this letter;
- Each step your facility is taking to prevent the recurrence of similar violations; and
- Samples of records that demonstrate proper recordkeeping.

Please submit your response to the attention of Patricia A. Clark, Compliance Officer, U.S. Food and Drug Administration, 300 Pearl Street, Suite 100, Buffalo, NY 14202, Telephone 716-551-4461, ext. 3165.

Finally, you should understand there are many FDA requirements pertaining to mammography. This letter pertains only to findings of our inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057, Telephone 1-800-838-7715, or through the internet at http://www.fda.gov.

Sincerely yours,

Edward W. Thomas
Acting District Director
New York District

cc: Priscilla F. Butler, M.S.
Director, Breast Imaging Accreditation Programs
Standards and Accreditation Department
American College of Radiology
1891 Preston White Drive
Reston, VA 22091

cc: Gerald O'Connor
New York State Department of Health
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cc: Nelson Warren
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